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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,399	06/13/2005	Rajender Kumar Potlapally	DRF 33-010	3144
70554	7590	10/26/2010	EXAMINER	
Reddy Us Therapeutics, Inc 3065 Northwoods Circle Norcross, GA 30071			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			10/26/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,399	<b>Applicant(s)</b> POTLAPALLY ET AL.	
	<b>Examiner</b> TAMTHOM N. TRUONG	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 2-26-10 (RCE).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 34 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34 and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## FIRST OFFICE ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-26-10 has been entered.

Claims 1-33, 35-37 and 58-64 are cancelled.

Claims 34 and 65-67 are pending.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 34, 66 and 67 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Chebiyyam et. al.** (WO'638).

Examples 39 and 40 describe the process of making potassium salt of Glitazone. The product is an off-white or white solid which could mean crystalline form since the term “solid”

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includes crystals as well. Thus, Chebiyyam et. al. (WO'638) inherently encompasses the claimed crystalline form of Glitazone potassium salt.

2. Claims 34, 66 and 67 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Lohray et. al.** (WO'097). The salt of Example 41 is Form I which is the same as the instant potassium salt.

The reference of Lohray was withdrawn in the previous action. However, applicant's remark citing paragraph [0016] **admits** that Form I of WO'097 is the same as the form claimed in this application, see the following statement:

[0016] The present invention also relates to a process for the preparation of 5-[4-[[3-Methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt **described** (*emphasis added*) in example 41 of our international application number PCT/US97/11522 (or Lohray et. al. WO 97/41097) which is designated as Form I.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 34 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Chebiyyam et. al.** (WO'638—cited previously) in view of **Gu et. al.** ("Polymorph Screening: . . .", J. Pharm. Sci., 11/2001, Vol. 90, No. 11, pp. 1878 – 1890). Although claim 65 has been amended to recite specific solvents and a temperature range, said process would still yield the same Form I, and thus, would be obvious in view of Example 40 of WO'638 and the solvent comparison of Gu et. al.

The process in Example 40 still recites many steps as those recited in the instant claim 65 and Example 2 (pages 11-12) of the disclosure. That is, the disclosed process has the following analogous steps:

- i. Glitazone base of step (i) was dissolved in xylene and methanol at about 80°C;
- ii. potassium t-butoxide was added at 60-70°C;
- iii. stirring at room temperature;
- iv. obtaining the precipitate of form I of the instant Glitazone potassium salt.

The disclosed process of Example 40 differs from the claimed process by using the solvent of "xylene and methanol" and not "acetonitrile and xylene". However, selecting xylene/acetonitrile or xylene/methanol would be within the level of the skilled chemist to obtain

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a desirable crystalline form because the choice of solvents depending on the following factors taught by Gu et. al. ("Polymorph Screening: . . .", J. Pharm. Sci., 11/2001, Vol. 90, No. 11):

- i. A fast nucleation rate, or a "relatively high solubility but moderate solute-solvent interactions" (see page 1885, right column, the last 4 sentences);
- ii. A weak hydrogen bonding propensity with a high solubility (to obtain a more stable polymorph) (see page 1887, left column, lines 6-8);
- iii. A balance of solubility and the strength of the solvent-solute interactions (see page 1887, right column, the last three lines).

In the reference of Gu et. al., Table 1 lists acetonitrile as the solvent preferred over methanol for forming a stable polymorph since it has a fairly high solubility with less hydrogen bonding (or less van der Waals force), and a fast nucleation rate.

Thus, at the time of the invention, it would have been obvious to select the combination of "xylene/acetonitrile" to replace "xylene/methanol" as a solvent for the process described in Example 40 because such a solvent would be a "solvent of choice" to produce the claimed potassium salt in view of the combined teachings above.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on Monday thru Friday (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/  
Examiner, Art Unit 1624

/James O. Wilson/  
**Supervisory Patent Examiner, Art Unit 1624**

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9-30-10